Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 May 2022

Verification of the efficacy of Bromhexine-hydrochloride in treatment of patients with COVID19 disease

Protocol summary

Study aim

This is a clinical trial that aims to confirm the effectiveness of this drug in preventing the deterioration of a patient with COVID19 from deterioration to hospitalization.

Design

Data will be collected by physicians and completed by completing a pre-made work protocol in admission articles and blood and throat PCR laboratory samples and will be sent to laboratories 24/7. The results of the patient's treatment and clinical course are followed up and recorded daily. All collected data are analyzed in SPSS software.

Settings and conduct

A placebo-controlled study involving 1,300 patients with COVID19 at Imam Reza Hospital based on clinical signs, imaging studies, and pre-PCR examination of nasopharyngeal biopsy results available the following day (at least 650 positive PCR cases target to report verified items).

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Male and female patients, 18 years and older All patients must meet all criteria for probable or confirmed COVID19 disease according to CSTE guidelines: Exclusion criteria Male and female patients under 18 years - Participate in other ongoing studies. - Pregnant or lactating woman Severe liver disease Severe kidney failure Refusal by the treating physician for clinical imbalance - Advanced active malignancy Patient in other clinical trials for COVID-19 within 30 days before / after ICF - Known allergies

Intervention groups

The intervention group will receive 8 mg bromhexine tablets every 8 hours for 14 days. Control group: receiving 3 placebo tab per day for 14 day

Main outcome variables

1. Evaluation of the efficacy of the drug in the parameters of clinical symptoms in comparison with the placebo group; 2. To examine the trend of laboratory changes (in CRP, LDH, NLR promotion) in bromhexine and placebo groups; 3. To evaluate the initial changes in IgM and IgG levels in the groups treated with bromhexine and placebo

General information

Reason for update

Acronym

COV-19

IRCT registration information

IRCT registration number: **IRCT20200818048444N1**
Registration date: **2020-09-15, 1399/06/25**
Registration timing: **prospective**

Last update: **2020-12-13, 1399/09/23**
Update count: **2**

Registration date

2020-09-15, 1399/06/25

Registrant information

Name

Khalil Ansarin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 8093

Email address

dr.ansarin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Verification of the efficacy of Bromhexine-hydrochloride in treatment of patients with COVID19 disease

Public title

Verification of the efficacy of Bromhexine-hydrochloride in treatment of patients with COVID19 disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years and older, both sexes Having home contact, unmasked contact with a patient with Covid-19 confirmed by RT-PCR or clinical evidence or radiography of pneumonia and acute respiratory distress syndrome (ARDS); No clinical signs of Covid-19 (fever, cough, dyspnea, shortness of breath, sore throat, extreme tiredness, digestive problems); No chronic respiratory problems or other illnesses that are mistaken for symptoms of COVID-19

Exclusion criteria:

Involvement with any other ongoing studies. Pregnant or breast feeding woman or with positive pregnancy test result for fetal safety Severe liver disease as a strong confounding factor Severe renal failure as a strong confounding factor Refusal by attending physician for no clinical equipoise Advanced active malignancy as a strong confounding factor Patient in other clinical trials for COVID-19 within 30 days before/after ICF as a confounding factor/s Other patient characteristics (not thought to be related to underlying COVID-19) that portend a very poor prognosis (e.g, severe liver failure, severe renal failure, and etc. May impact primary and other clinical endpoints- Known allergy to study drug or its ingredients related to renin-angiotensin system (RAS), or frequent and/or severe allergic reactions with multiple medications for patient protection purposes Other uncontrolled disease, as judged by investigators that may influence study endpoint and other clinical outcome

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **1300**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the entry and exit criteria, through random allocation by variable block method, individuals are divided into two groups of control and experimental. Using Random Sequence Generator, groups are created and people are placed in one of these two groups based on the reference sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a two-way blind study. In this study, the subject and the researcher are both unaware of the drug used by individuals. The placebo and the main drug are placed in similar boxes with specific codes and are delivered to the patient by a third party. Medication information will not be visible to the therapist.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Committee on Research Ethics (Studies in Human Subjects)

Street address

Third Floor / Tabriz University of Medical Sciences, Central Building No. 2/Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-08-24, 1399/06/03

Ethics committee reference number

IR.TBZMED.REC.1399.827

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Test for the presence or absence of nucleic acid in the corona virus

Timepoint
15 days after the intervention
Method of measurement
real-time PCR

2

Description
Serum IgM and IgG levels
Timepoint
15 days after the intervention
Method of measurement
Immunology test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will receive 8 mg bromhexine tablets every 8 hours for 14 days.
Category
Prevention

2

Description
Control group: will receive 3 placebo tablets per day for 14 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Khalil Ansarin
Street address
Imam Reza Hospital, Golgasht St.
City
Tabriz
Province
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Postal code
5166614756
Phone
+98 41 3334 7054
Email
imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Central Building of University of Medical Sciences/ Golgasht St./ Azadi St./ Tabriz
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East Azarbaijan
Postal code
5142954481
Phone
+98 41 3335 7310
Email
Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Ministry of Health and Medical Education
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khalil Ansarin
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can potentially be shared after unidentified individuals.
When the data will become available and for how long
Spring 1400
To whom data/document is available
Data is allowed for all researchers after submitting an access request and confirming it
Under which criteria data/document could be used
In order to use the data, researchers must first identify and send the required items and data upon request, after which the data will be delivered.
From where data/document is obtainable
By email dr.ansarin@gmail.com or postal code: 5142954481
What processes are involved for a request to access data/document
The researcher must state his request in a letter. After agreeing to his request, the data will be emailed to him in Excel or Spss.
Comments